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ImmunoCellular Therapeutics Presents Updated ICT-107 Phase 2 Survival and Immune Response Data at the Society for Neuro-Oncology Annual Meeting 2015

Data support phase 3 registration trial incorporating key design modifications to potentially optimize outcomes

LOS ANGELES, Nov. 20, 2015 /PRNewswire/ -- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT:IMUC) announced the presentation today of recently updated overall survival (OS) results and immune response data from the phase 2 trial of ICT-107 in patients with newly diagnosed glioblastoma. ICT-107 is a dendritic cell-based immunotherapy targeting multiple tumor-associated antigens on glioblastoma stem cells. The data are being presented at the 20th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology, being held in San Antonio, TX. The data from the phase 2 trial continue to indicate a survival advantage in the ICT-107 treated group compared to the control group. The data also show a significant association between immune response and survival, especially in HLA-A2 positive (HLA-A2+) patients, which is the target patient population for the phase 3 registration trial.

- OS results were analyzed at three years after the last patient enrolled. For the 124-patient intent-to-treat population (ITT), median OS was 1.6 months or 10% better for ICT-107 patients than control. The difference in the Kaplan-Meier (KM) survival curves for this patient population was not statistically significant.
- Updated OS results for the pre-specified subgroup of HLA-A2+ patients continue to support selecting this patient population alone for a well powered phase 3 trial. For the MGMT methylated, HLA-A2+ PP population, median OS was 13.8 months or 58% better for ICT-107 treated patients than control. For the MGMT unmethylated, HLA-A2+ per-protocol (PP) population, median OS was 4.0 months or 34% better for ICT-107 treated patients than control. The differences in the KM survival curves for these two pre-specified phase 2 sub-populations were not powered for, and did not achieve, statistical significance.
- ELISPOT evaluation of antigen-specific immune response demonstrated a more frequent immune response in HLA-A2+ patients compared with HLA-A1 patients, and this difference was statistically significant. This increased immune response in HLA-A2+ patients further supports the selection of HLA-A2+ patients exclusively for inclusion in the phase 3 trial.
- In HLA-A2+ patients, immune response was shown to be associated with survival. 60% of ICT-107 treated patients demonstrated a statistically significant immune response compared to only 36% of control patients. In a KM comparison of OS for immune responders versus non-responders, the responder curve showed a statistically significant survival benefit with a log-rank p-value of 0.0084. For ICT-107 treated patients, the KM comparison of OS for responders versus non-responders showed a statistically significant survival benefit with a log-rank p-value of 0.0147. The Company believes that the relationship between immune response and OS supports the phase 3 design improvement of adding more ICT-107 doses for patients in the first year of the protocol.
- Immune response did not differ statistically for MGMT methylated compared to unmethylated patients. This result supports including both MGMT types of patients in phase 3 testing.
- Of particular interest was the unexpected finding that there was an increased immune response in some control patients post-treatment. One potential explanation is that the phase 2 control (activated dendritic cells without peptide loading) was immunologically active. The phase 3 design employs a different control comprising the patients' own monocytes, which are less immunologically active than dendritic cells. This control could help clarify a potential survival difference between ICT-107 and control treated patients.

The data are being presented at SNO by John S. Yu, MD, Founder of ImmunoCellular Therapeutics. Dr. Yu commented: "The final data from the phase 2 trial continue to demonstrate the therapeutic value of ICT-107 as a potential treatment for patients with newly diagnosed glioblastoma, and strongly support advancing to phase 3 testing. The clear association between immune response and survival is an important finding that we believe validates the immunotherapeutic mechanism of ICT-107 and strengthens our optimism for the phase 3 trial."

Andrew Gengos, ImmunoCellular Chief Executive Officer, said: "Based on these newly updated phase 2 survival results and the supporting immune response data, we are confident of the design improvements we have built into the phase 3 trial, and look forward to treating our first patient in the coming weeks. The phase 3 trial initiation represents a major milestone in

the company's path toward building a leading cancer immunotherapy company."

Phase 3 Registration Trial Sites Open; First Patient Anticipated to be Treated Soon

The phase 3 registrational trial of ICT-107 is designed as a randomized, double-blind, placebo-controlled study of over 400 HLA-A2+ subjects, which will be conducted at about 120 sites in the US, Canada and the EU. The primary endpoint in the trial is overall survival, which the FDA and EU regulators have stated is the appropriate endpoint for registrational clinical studies in glioblastoma. Secondary endpoints include progression-free survival and safety, as well as overall survival in the two pre-specified MGMT subgroups.

Multiple clinical trial sites have been opened for patient enrollment in the US, with additional sites anticipated to open in Canada and Europe in the coming weeks and months.

ImmunoCellular has reached agreement with the US FDA on a Special Protocol Assessment (SPA) relative to the primary and secondary endpoints as well as the statistical plan for the phase 3 trial. ImmunoCellular has also been awarded a $19.9 million grant from the governing Board of the California Institute for Regenerative Medicine (CIRM), California's stem cell agency, to implement the phase 3 registration trial.

Background on the ICT-107 Phase 2 Trial

The ICT-107 phase 2 trial was a randomized, double-blind, placebo-controlled phase 2 study of the safety and efficacy of ICT-107 in patients with newly diagnosed glioblastoma multiforme following resection and chemoradiation. ICT-107 is an intradermally administered autologous immunotherapy consisting of the patient's own dendritic cells pulsed with six synthetic tumor-associated antigens: AIM-2, MAGE-1, TRP-2, gp100, HER-2, IL-13Rα2. The placebo control consisted of the patient's unpulsed dendritic cells.

A total of 124 patients were randomized at 25 clinical trial sites in the US. One third of the patients or 43 patients were treated with placebo, and the treatment arm included two thirds or 81 patients. All patients in the trial received standard-of-care temozolomide. The regimen was four induction doses of ICT-107 after chemoradiation, and then maintenance doses until the patient progresses. The primary endpoint of the trial was OS, defined as the time from randomization until date of death or the last date the patient is known to be alive. Secondary endpoints included PFS, defined as the time from randomization until the date of documented progressive disease or death, whichever occurs first, or the last date the patient is known to be alive and progression-free if progression or death is not observed. Other secondary endpoints included the rates of OS and PFS at six months after surgery, then assessed every three months until the end of the study. Safety and immune response were additional secondary endpoints.

For patients, families and physicians seeking additional information about the ICT-107 phase 3 trial, please consult www.clinicaltrials.gov.

About ImmunoCellular Therapeutics, Ltd.

ImmunoCellular Therapeutics, Ltd. is a Los Angeles-based clinical-stage company that is developing immune-based therapies for the treatment of brain and other cancers. The phase 3 registrational trial of lead product candidate, ICT-107, a dendritic cell-based immunotherapy targeting multiple tumor-associated antigens on glioblastoma stem cells, is open for patient enrollment. ImmunoCellular's pipeline also includes: ICT-121, a dendritic cell immunotherapy targeting the CD133 antigen on stem cells in recurrent glioblastoma; ICT-140, a dendritic cell immunotherapy targeting antigens on ovarian cancer stem cells; and the Stem-to-T-cell research program which engineers the patient's hematopoietic stem cells to generate antigen-specific cancer-killing T cells.

Forward-Looking Statements for ImmunoCellular Therapeutics

This press release contains certain forward-looking statements, including statements regarding the development and commercialization of ICT-107, initiation of a phase 3 study of ICT-107, the advancement of the ICT-121 phase 1 trial, the development of our preclinical Stem-to-T-cell program and our ability to achieve our other clinical, operational and financial goals. These statements are based on ImmunoCellular's current expectations and involve significant risks and uncertainties, including those described under the heading "Risk Factors" in ImmunoCellular's most recently filed quarterly report on Form 10-Q and annual report on Form 10-K. Except as required by law, ImmunoCellular undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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